

Quality control methods for herbal materials



World Health
Organization

Quality control methods for herbal materials

Updated edition of Quality control methods for medicinal plant materials, 1998



**World Health
Organization**

WHO Library Cataloguing-in-Publication Data

Quality control methods for herbal materials.

Updated edition of *Quality control methods for medicinal plant materials*, 1998

1. Plants, Medicinal. 2. Medicine, Herbal. 3. Medicine, Traditional. 4. Quality control. 5. Manuals. I. World Health Organization.

ISBN 978 92 4 150073 9

(NLM classification: QV 766)

© World Health Organization 2011

All rights reserved. Publications of the World Health Organization can be obtained from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: bookorders@who.int). Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to WHO Press, at the above address (fax: +41 22 791 4806; e-mail: permissions@who.int).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

Printed in Malta.

Contents

Acknowledgment	v
Preface to the first edition (1998).....	vii
Preface to the updated edition	ix
Note to the reader	xi
1. General notices	1
2. Powder fineness and sieve size.....	5
3. General advice on sampling.....	7
4. Determination of foreign matter	9
5. Macroscopic and microscopic examination.....	11
6. Thin-layer chromatography.....	23
7. Determination of ash	29
8. Determination of extractable matter.....	31
9. Determination of water and volatile matter.....	33
10. Determination of volatile oils.....	37
11. Determination of bitterness value	41
12. Determination of haemolytic activity	43
13. Determination of tannins	45
14. Determination of swelling index	47
15. Determination of foaming index.....	49
16. Determination of pesticide residues	51
17. Determination of arsenic and toxic metals.....	67
18. Determination of microorganisms.....	75
19. Determination of aflatoxins.....	85

20. Radioactive contamination	87
21. Culture media and strains used for microbiological analysis	89
22. Specifications for adsorbents for use in thin-layer chromatography	93
23. Reagents and solutions	99
References	125
Selected bibliography	127
Glossary	129
Annex WHO good practices for pharmaceutical quality control laboratories	135

Acknowledgements

The World Health Organization wishes to express its appreciation for the generous financial support provided by the Government of Japan for the publication of this document.

WHO acknowledges its indebtedness to approximately 260 reviewers, including members of the organization's Expert Advisory Panel on Traditional Medicine and Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations, WHO collaborating centres for traditional medicine, and national regulatory authorities in over 114 countries who provided national information, comments and advice on the draft texts. The preparation of this document benefited from technical support received from relevant professional bodies and nongovernmental organizations.

WHO also wishes to thank the members of the WHO Expert Committee on Specifications for Pharmaceutical Preparations, which met in 2004 and 2007 and held consultation meetings in 2005 and 2006, for their review of, technical guidance on, and endorsement of the updated contents of this publication.

The photograph on the front cover was kindly provided by Dr Yukihiro Goda, Head of the Division of Pharmacognosy, Phytochemistry and Narcotics, at the National Institute of Health Sciences, Ministry of Health, Labour and Welfare, Tokyo, Japan.

Preface to the first edition (1998)

Plant materials are used throughout developed and developing countries as home remedies, over-the-counter drug products and raw materials for the pharmaceutical industry, and represent a substantial proportion of the global drug market. It is therefore essential to establish internationally recognized guidelines for assessing their quality. The World Health Assembly — in resolutions WHA31.33 (1978), WHA40.33 (1987) and WHA42.43 (1989) — has emphasized the need to ensure the quality of medicinal plant products by using modern control techniques and applying suitable standards. This manual describes a series of tests for assessing the quality of medicinal plant materials. The tests are designed primarily for use in national drug quality control laboratories in developing countries, and complement those described in *The international pharmacopoeia*,¹ which provides quality specifications only for the few plant materials that are included in the WHO Model List of Essential Drugs.² This manual does not constitute a herbal pharmacopoeia, but a collection of test procedures to support the development of national standards based on local market conditions, with due regard to existing national legislation and national and regional norms. Publications containing relevant specifications and standards, including those related to the food industry, are listed in the References and Bibliography.

The test methods described here are the best methods currently available. The manual will be revised as needed to incorporate improvements and additional tests and to reflect developments in work being carried out at national and regional levels, including projects aimed at finding replacements for toxic reagents.

In addition to the test methods, some suggestions regarding general limits for contaminants are included. They should be considered as a basis for establishing national limits. WHO is not currently able to recommend limits for contaminants since these are too diverse and there is a lack of consensus. For instance, the draft proposal for limits for some pesticides published in *Pharmeuropa*, 1993, 5(1): 19, is far more restrictive than that proposed here.

预览已结束，完整报告链接和二维码如下：

https://www.yunbaogao.cn/report/index/report?reportId=5_28734

